K014209

JAN 1 8 2002

EXHIBIT 2

PadPro LLC.
5643 Plymouth Rd.
Ann Arbor, Mi 48105
Phone: 734-663-0132
Fax: 734-663-1306
Contact: Cliff Poppy, President
December 12, 2000

510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
   Proprietary-Trade Name: "PadPro" 2001, 2001-S, 2001-C, 2001-EPS Multifunction Electrodes
   Classification Name: Electrode, Electrocardiograph, Multi-Function; MLN
   Common/Usual Name: Defibrillator Electrode

2. Equivalent legally marketed device: This identical in function to the Katecho KDP-60A (K002806) and nearly identical in design.

3. Indications for Use: The PadPro radiotransparent external electrodes are indicated for use in external pacing, defibrillation and monitoring applications as a non-sterile, disposable device for single patent use only. The electrodes provide the conductive interface between the defibrillator and/or the external transcutaneous (noninvasive) cardiac pacemaker and the patient's skin. The electrode is intended for use on adult patients. When a patient requires defibrillation, cardioversion or external pacing, these electrodes will be applied to the patient and connected to the instrument. This device is intended for use on defibrillators whose output is classified as low power (360 joule maximum).

4. Description of the Devices: Features & Benefits:
   The electrodes are multifunction because they can be used for defibrillation, pacing, cardioversion, and monitoring. PadPro electrodes can be used on all makes and models of defibrillator, including all of the Bi-Phasic units. Radio transparent. "One Pad System" enables the pads to stay with the patient as they move through departments. PadPro has an electrode for any clinical need or patient situation. The high tack adhesive gel allows PadPro electrodes to be repositioned multiple times. PadPro can provide onsite conversion of current cables to accept the PadPro electrodes. The polymer adhesive gel allows superior contact for uniform current distribution and more effective defibrillation and pacing. PadPro's adapter system simply plugs into the OEM cable. Standardization of products - One connector can be used throughout the institution, no matter what brand or model of defibrillation/pacing unit is being used. All PadPro products are Latex free.

Model differentiation:

Model	**Feature/difference**
2001	Standard connector (2 contacts)
2001-S	Split connector (separate contacts)
2001-C	Radiotransparent leadwire (carbon fiber)
2001-EPS	Larger rear pad, 334 cm sq.

5. Safety and Effectiveness, comparison to predicate device:

Comparison Areas	Katecho KDP-60A (K002806)	"PadPro" Defibrillator Electrodes
Indications for use	For use as disposable electrodes for automatic and manual external defibrillators for monitoring, pacing, cardioversion, and defibrillation	SAME
Where used	Hospitals and Paramedic situations	SAME
Basic features	Radiotransparent, non sterile, latex free, single patient use, self adhesive, in sealed foil pouch.	
Standard met	International Electrotechnical Commission (IEC) 601-1: Medical Electrical Equipment 601-1 (1988) Part 1: General requirements for safety Amendment No. 1 (1991) Amendment No. 2 (1995 and Sec.898.12 Performance standard; ANSI/AAMI DF-39 (3.3.19) standard, self adhesive electrodes for monitoring and defibrillation	SAME

6. Conclusion In all respects, the PadPro System Defibrillator Electrodes are substantially equivalent to other electrodes that are legally marketed for this purpose. The device meets the standards referenced above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 8 2002

PadPro LLC.
c/o Mr. Daniel Kamm, P.E.
Kamm & Associates
P.O. Box 7007
Deerfield, IL 60015

Re: K014209
Trade Name: "PadPro" 2001, 2001-S, 2001-C, and 2001-EPS Multifunction Electrodes
Regulation Number: 21 CFR 870.1025
Regulation Name: Accessory to Automatic External Defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ
Dated: December 20, 2001
Received: December 21, 2001

Dear Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

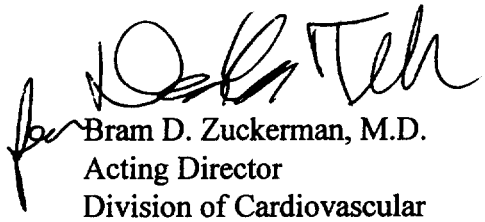
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

j) Indications for Use

510(k) Number K014209

Device Name: "PadPro" 2001, 2001-S, 2001-C, 2001-EPS Multifunction Electrodes

Indications for Use:

The PadPro radiotransparent external electrodes are indicated for use in external pacing, defibrillation and monitoring applications as a non-sterile, disposable device for single patent use only. The electrodes provide the conductive interface between the defibrillator and/or the external transcutaneous (noninvasive) cardiac pacemaker and the patient's skin. The electrode is intended for use on adult patients.
When a patient requires defibrillation, cardioversion or external pacing, these electrodes will be applied to the patient and connected to the instrument. This device is intended for use on defibrillators whose output is classified as low power (360 joule maximum).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K014209